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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/772,040

02/04/2004

Robert F. Rioux

03-253 US

3903

23410

7590

10/16/2006

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/772,040

Applicant(s)

RIOUX ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-46 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-46 and 57-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/15/06</u> . | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 15, 2006 has been entered.

The examiner of record has discovered new prior art which is deemed to read on the amended claims. The new prior art is deemed to read on subject matter previously indicated as allowable. The following is a complete action on the merits of the pending claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 8-12, 15, 16, 18, 26, 27, 29, 31-35, 37-40, 57, 59 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Chia et al (5,916,856).

Chia et al disclose an ablation probe that includes an elongate shaft (21 – see Figure 2), an ablative element (11) disposed on the end of the shaft, a lumen extending within the shaft and a porous structure (21 – see col. 5, lines 25-45) extending the entirety of the shaft. Chia et al specifically disclose that the pores may be in the size

range of 5-1000 microns (col. 5, lines 28-29). The percent porosity is deemed to inherently be within the range as set forth in the claims, and the examiner maintains the Chia et al catheter may be broadly interpreted as being "rigid", at least rigid enough for introduction into the vasculature. Chia et al disclose an RF electrode as the ablation element, and also teach that the ablation electrodes may be made from a porous material. A pump is used to infuse fluid through the catheter (col. 5, lines 10-13). In view of the pore size disclosed by Chia et al, the structure is deemed to be "microporous" (see also col. 5, lines 29-30).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 14, 19-21, 23-25, 30, 36, 41-46, 58 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chia et al ('856) in view of the teaching of Fung et al (6,602,242).

The Chia et al microporous catheter shaft has been addressed previously. Chia et al fail to specifically disclose pores that are interconnected. The examiner maintains that pores of such a size would inherently have an interconnected structure. However, to more accurately show such a feature, attention is directed to the Fung et al reference.

Fung et al disclose another porous ablation catheter and specifically teach that pores in the perfusion electrode may be interconnected (see Abstract and col. 8, line 35) to provide perfusion through the member.

To have provided the Chia et al device with interconnected pores for providing the fluid through the porous member would have been an obvious design consideration for one of ordinary skill in the art, particularly since Fung et al teach that it is generally known to provide porous structures with interconnected pores.

Claims 1-6, 8-13, 15-18, 26-29, 31-35, 37-40, 57, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (6,669,692) in view of the teaching of Chia et al ('856).

The Nelson et al device has been addressed in previous Office actions. It includes an elongate shaft (60) having a distal end with an ablative element (52) disposed on the distal end. A lumen (65) extends through the elongate shaft and a porous structure (62) extends along substantially the entire length of the shaft and in communication with the lumen. The only feature not expressly disclosed by Nelson et al is the size of the pores. Regarding the porosity, the examiner maintains that the percent porosity would inherently, or at least obviously, be located within applicant's claimed range to provide the uniform fluid flow necessary to provide the cooling and avoidance of "hot spots" on the electrode surfaces. One of ordinary skill in the art would further recognize that the porosity would obviously be changed to provide the necessary

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fluid flow depending on the tissue being treated, the area contacted and the energy being used.

As addressed above, Chia et al disclose an analogous ablation probe having pores, and specifically disclose a range of pores sizes in the micron range that is acceptable for perfusing tissue during ablation.

With regard to claims 3 and 31, it is noted that the term "rigid" is a very broad term. In Nelson et al, the plastic shaft (60) is rigid enough to provide support for the electrode, yet flexible to afford maneuverability of the distal section. Inasmuch as the plastic shaft is used to provide rigidity to the section, it is deemed to fall within the broad interpretation of the term "rigid".

Concerning claims 4 and 28, it is noted that the plastic tube is surrounded by a wound electrode (61) which is metallic and has pores (i.e. spacings). This metallic electrode is deemed to be part of the porous nature of the elongate tube.

Nelson provides a proximal connector for electrical and fluid connections, and inherently provide a means (i.e. a pump) to provide the fluid through the catheter lumen.

To have provided the Nelson et al device with pores having a size in the micron range for perfusing an ablation electrode would have been an obvious design consideration for one of ordinary skill in the art, particularly since Chia et al teach that such pore sizes are within the known range of ablation perfusion catheters.

Claims 7, 14, 19-25, 30, 36, 41-46, 58 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al ('692) and Chia et al ('856) and further in view of the teaching of Fung et al (6,602,242).

The combination of the Chia et al teaching with the Nelson et al catheter has been previously addressed. Also addressed previously is the teaching of Fung et al providing interconnecting pores in the perfusion substrate.

To have provided the Nelson et al catheter, as modified by the teaching of Chia et al, with interconnected pores is deemed an obvious design consideration for one of ordinary skill in the art, particularly since Fung et al teach that it is known to provide perfusion devices with interconnected pores to provide fluid to tissue during an ablation procedure.

### ***Conclusion***

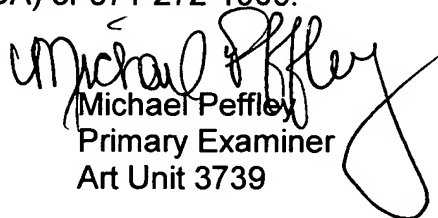
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bencini et al (6,666,864) and Tu et al (6,217,576) disclose alternative perfusion ablation devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Michael Peffley  
Primary Examiner  
Art Unit 3739

mp  
October 11, 2006